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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,729	06/19/2001	Luis A. Davila	CRD-0938	2529

27777 7590 02/28/2003
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EXAMINER

GILPIN, CRYSTAL M

ART UNIT PAPER NUMBER

3738

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No. 09/884,729	Applicant(s) DAVILA ET AL.	
	Examiner Crystal M Gilpin	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 9, 11 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Claims 28-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected method of manufacturing a medical device, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claim Objections

1. Claim 11 is objected to because of the following informalities: It is suggested to
✓ change the word "open" to "opening" in the following sentence – defines a substantially elliptical *open* having a-.
2. Claim 9 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim
✓ 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 9 and 18 recite the limitation "substantially tubular" in –the radius of curvature of the substantially tubular marker-. There is insufficient antecedent basis for this limitation in the claim.

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2. Claims 1, 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "tubular" in claims 1, 9 and 18 is indefinite because it is used by the claim to mean "cylindrical," while the accepted meaning is "a hollow elongated cylinder." Therefore, for the prosecution of this case, the term "tubular" as applied to the marker is accepted as being synonymous cylindrical.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-14, 16-23 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Globerman et al. (WO 97/33534).

Regarding claims 1-6, 9, 10, 12-14, 18, 19 and 21-23, Globerman et al. disclose of a intraluminal medical device (Figures 10-12) made of a material such as nitinol, with a first collapsed diameter that is expandable to a second anchoring diameter, with at least one marker housing (Ref. Number 29) and marker insert (Ref. Number 25) with the equal radii of curvature. The marker insert (Fig. 11, Ref. Num. 37) is substantially cylindrical to fit within the substantially tubular marker housing (Fig. 11, Ref. Num. 35). Nitinol is well known in the art as

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a superelastic alloy that is comprised of about 50% Nickel and the remainder Titanium.

Globerman et al. further disclose that the marker housing is an integral part of the medical device structure (Figure 10), is made of the same material as the device and that the insert material is a different material such as tantalum (Page 3, Lines 5-6) and has a higher radiopacity than the device material.

Regarding claims 7, 16, 25, Globerman et al. disclose that the marker insert is secured to the marker housing by frictional engagement (Page 5, Lines 1-7).

Regarding claims 8, 17 and 26 Globerman et al. disclose that the marker insert is secured in the marker housing by a protruding edge (Figure 9, Ref. Number 16).

Regarding claims 11 and 20, Globerman et al. disclose of a marker housing embodiment that is substantially elliptical (Figure 8, Ref. Number 14).

Regarding claim 27, Globerman et al. disclose that there could be from 2 to 20 markers placed longitudinally or radially along the tubular body (Page 8, Lines 8-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman et al. (WO 97/33534) in view of Imran (USPN 6,022,374).

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Regarding claims 15 and 24, Globerman et al. disclose a stent with radiopaque marker inserts, however they lack the teaching of the diameter of the inserts. Imran teaches of a stent with radiopaque markers that include an insert and a projection with a diameter of 0.015 inches (Column 3, Lines 17-29) to fit within the eyelet. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Globerman et al. to have marker inserts with a diameter of 0.02 inches to frictionally engage the marker housing.

Response to Arguments

Applicant's arguments filed in regards to the restriction requirement have been fully considered but they are not persuasive. The classification of the claims in different categories ^{necessitates} ~~prevents the necessitation of~~ a burdensome search. The restriction is upheld on the grounds that the inventions of Group I and Group II are distinct and require searches in different classes.

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02-24-03

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mathis et al. (USPN 6,129,755)

Globerman et al. (USPN 6,402,777)

Dor et al. (USPN 6,334,871)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg

February 24, 2003


Paul B. Prebille
Primary Examiner